CENTER FOR FOOD SAFETY

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 21, 2016

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Sixty-Day Notice of Intent to Sue the Food and Drug Administration Pursuant to the Endangered Species Act

Re: Final Environmental Assessment and Finding of No Significant Impact for the Release of Genetically Engineered Mosquitoes as an Investigational New Animal Drug

Acting Commissioner Califf,

The Food and Drug Administration (FDA) is hereby notified, unless the violations described herein are remedied within sixty days, that the organizations listed below intend to sue FDA and its Acting Commissioner Dr. Calliff (collectively, FDA), for violations of the Endangered Species Act (ESA), 16 U.S.C. § 1531 *et seq.*, associated with FDA's final environmental assessment (EA) and Finding of No Significant Impact (FONSI) for the release of genetically engineered (GE) *Aedes aegypti* mosquitoes as an investigational new animal drug (INAD). FDA has violated and remains in violation of Section 7 of the ESA by, *inter alia*, failing to insure, through consultation with the National Marine Fisheries Service (NOAA Fisheries) and the U.S. Fish and Wildlife Service (FWS) (collectively, the Services), that its approval of the release of GE mosquitoes is not likely to jeopardize the continued existence of any threatened or endangered species and/or result in the destruction or adverse modification of the critical habitat of any listed species. Center for Food Safety (CFS) provides this letter pursuant to Section 11(g) of the ESA, 16 U.S.C. § 1540(g), on behalf of Florida Keys Environmental Coalition, Food & Water Watch, Foundation Earth, Friends of the Earth, and International Center for Technology Assessment (ICTA) (collectively, the concerned parties).

I. IDENTITY OF THE PARTIES GIVING NOTICE

The name and location of the concerned parties giving notice of intent to sue under the ESA are:

Center for Food Safety
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Florida Keys Environmental Coalition
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Food & Water Watch
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Foundation Earth
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Friends of the Earth
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International Center for Technology Assessment
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III. REQUIREMENTS OF THE ESA

Section 7 of the ESA requires federal agencies such as FDA, in consultation with the expert wildlife agencies, to insure that any action authorized, funded, or carried out by the agency is not likely to jeopardize the continued existence of any threatened or endangered species, or result in the destruction or adverse modification of the critical habitat of such species. 16 U.S.C. § 1536(a)(2). An action is considered to result in jeopardy where it would reasonably be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of that species. 50 C.F.R. § 402.02. "Action" is broadly defined to include all activities or programs of any kind authorized, funded, or carried out by federal agencies, including actions directly or indirectly causing modifications to the land, water, or air. *Id.*

To carry out this substantive mandate, the ESA and its implementing regulations require all federal agencies to consult with the Services on the effects of their proposed actions. 16 U.S.C § 1536(a)(2); 50 C.F.R. §§ 402.12-402.16. This process begins with the requirement that the "action" agency, such as FDA here, ask the Services whether any listed or proposed species may be present in the area of the agency action. 16 U.S.C. § 1536(c)(1); 50 C.F.R. § 402.12. If listed or proposed species may be present, the action agency must prepare a "biological assessment" to determine whether the listed species is likely to be affected by the proposed action. *Id.* The biological assessment generally must be completed within 180 days. 16 U.S.C. § 1536(c)(1); 50 C.F.R. § 402.12(i).

If the action agency determines the action "may affect" a listed species or critical habitat, the action agency must formally consult with NOAA Fisheries and/or FWS to "insure" that the action is "not likely to jeopardize the continued existence" of that species, or "result in the destruction or adverse modification of habitat … determined … to be critical…." 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14(a).[1] The threshold for a finding of "may affect" is extremely low. A triggering effect need not be significant; rather "any possible effect, whether beneficial, benign, adverse, or of an undetermined character, triggers the formal consultation requirement…." Interagency Cooperation—Endangered Species Act of 1973, as Amended; Final Rule, 51 Fed. Reg. 19,926, 19,949 (June 3, 1986); Final ESA Section 7 Consultation Handbook at xvi (Mar. 1998) (defining "may affect" as "the appropriate conclusion when a proposed action may pose *any* effects on listed species….").

If a proposed action "may affect" a listed species or designated critical habitat, formal consultation is required unless the Service(s) concur in writing with an action agency's finding that the proposed action "is not likely to adversely affect" listed species or designated critical habitat. 50 C.F.R. §§ 402.02, 402.13(a), 402.14 (a). This "informal consultation" process consists of discussions and correspondence between the Services and the action agency and is designed to assist the action agency in determining whether formal consultation is required. 50 C.F.R. § 402.13(a). An action is "likely to adversely affect" protected species and formal consultation is required if: "any adverse effect to listed species may occur as a direct or indirect result of the proposed action or its interrelated or interdependent actions, and the effect is not discountable, insignificant, or beneficial." *Endangered Species Consultation Handbook*, March 1998, p. xv.

To complete formal consultation, NOAA Fisheries and/or FWS must provide FDA with a "biological opinion" explaining how the proposed action will affect the listed species or habitat. 16 U.S.C. § 1536(b); 50 C.F.R. § 402.14. In fulfilling Section 7 consultation duties, agencies are required to use the best scientific and commercial data available. 16 U.S.C. § 1536(a)(2). Until the expert wildlife agency issues a comprehensive biological opinion, the action agency may not commence the action. *Pac. Rivers Council*, 30 F.3d at 1056-57; *and see* 16 U.S.C. § 1536(d). Further, during consultation, FDA is prohibited from making any irreversible or irretrievable commitment of resources with respect to the agency action which may foreclose the formulation or implementation of any reasonable and prudent alternative measures. 16 U.S.C. § 1536(d).

If the expert wildlife agency concludes that the proposed action "will jeopardize the continued existence" of a listed species, the biological opinion must outline "reasonable and prudent alternatives," if any exist. 16 U.S.C. § 1536(b)(3)(A). If the biological opinion concludes that the action is not likely to jeopardize the continued existence of a listed species,

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[1] "Jeopardize" means taking action that "reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of that species." 50 C.F.R. § 402.02. A species' "critical habitat" includes those areas identified as "essential to the conservation of the species" and "which may require special management considerations or protection." 16 U.S.C. § 1532(5)(A).

and will not result in the destruction or adverse modification of critical habitat, NOAA Fisheries and/or FWS must provide an "incidental take statement," specifying the amount or extent of such incidental taking on the listed species, any "reasonable and prudent measures" that they consider necessary or appropriate to minimize such impact, and setting forth the "terms and conditions" that must be complied with by FDA to implement those measures. 16 U.S.C. § 1536(b)(4); 50 C.F.R. § 402.14(i). In order to monitor the impacts of incidental take, FDA must monitor and report the impact of its action on the listed species to the Services as specified in the incidental take statement. 16 U.S.C. § 1536(b)(4); 50 C.F.R. § 402.14(i)(1)(iv), (i)(3). If during the course of the action the amount or extent of incidental taking is exceeded, FDA must immediately re-initiate consultation with the Services. 50 C.F.R. § 402.14(i)(4).

Federal agencies have an independent and substantive obligation to insure that their actions are not likely to jeopardize the continued existence of endangered or threatened species or adversely modify critical habitat. Indeed, Section 7(a)(1) of the ESA requires FDA, in consultation with and with the assistance of the Services, to utilize its authorities in furtherance of the purposes of the ESA by carrying out programs for the conservation of endangered and threatened species. 16 U.S.C. § 1536(a)(1).

Federal agencies also have a continuing duty under Section 7 of the ESA to re-initiate consultation whenever "new information reveals effects of the action that may affect listed species or critical habitat in a manner or to an extent not previously considered," where the action in question is "subsequently modified in a manner that causes an effect to the listed species or critical habitat that was not considered in the biological opinion," or where "a new species is listed or critical habitat designated that may be affected by the identified action." 50 C.F.R. § 402.16(b)-(d).

Finally, Section 9(a) of the ESA, 16 U.S.C. § 1538(a), prohibits the "take" of an endangered species by any person. This prohibition has generally been applied to many species listed as "threatened" through the issuance of regulations under Section 4(d) of the ESA. 16 U.S.C. § 1533(d); 50 C.F.R. § 17.31(a). "Take" includes actions that kill, harass, or harm a protected species. 16 U.S.C. § 1532(19). "Harass" is defined to include acts that create the likelihood of injury to wildlife by annoying it to such an extent as to significantly disrupt normal behavioral patterns. 50 C.F.R. § 17.3. "Harm" includes significant habitat modification or degradation that actually kills or injures wildlife by significantly impairing essential behavioral patterns. *Id.*; 50 C.F.R. § 222.102.

IV. FACTUAL BACKGROUND AND LEGAL VIOLATIONS

Oxitec, Ltd. (Oxitec) created its GE mosquito (OX513A) by inserting two genes into the egg of an *Aedes aegypti* mosquito. One gene, a fluorescent marker, helps distinguish the GE mosquito from natural ones. The other gene forces the GE mosquito to rely on the antibiotic tetracycline, which Oxitec inserts into its food in the lab. When Oxitec releases GE mosquitoes into the wild, the mosquito is unable to survive without the presence of the antibiotic. Within days, the males and any offspring they produce will allegedly die off, thereby reducing the population of wild *Aedes aegypti* mosquitoes. Oxitec's mosquito control program involves the repeated release of GE male *Aedes aegypti* to mate with wild female *Aedes aegypti*.

FDA has now approved the unprecedented release of millions of GE mosquitoes over two years in Key Haven, Monroe County, Florida, as an investigational new animal drug, pursuant to authority it purports to extend from its Federal Food Drug and Cosmetic Act (FFDCA) regulation of "new animal drugs." 80 Fed. Reg. 73,104 (Nov. 24, 2015). The GE mosquito has been genetically engineered by British biotechnology company Oxitec to express conditional lethality and a fluorescent marker. This GE mosquito release is the first ever that FDA has approved. In so doing, FDA has made erroneous and unilateral assumptions that its approval action will have "no effect" on protected species and/or their critical habitat. *See* FDA, Finding of No Significant Impact at 6-7 (Aug. 5, 2016). Yet dozens of protected species that live or occur in the area of the release may be affected by the approval. *See* FDA, Environmental Assessment (EA) at 45-46 and Appendix B (Aug. 5, 2016). FDA's "no effect" decision for these species was contrary to law. In addition, FDA admitted that while its approval action may affect at least one protected species, the Stock Island tree snail (*Orthalicus reses*), its approval was still "not likely to adversely affect" the protected snail. *Id.* That decision was also contrary to law. Pursuant to its duties under the ESA, FDA was required to consult with the expert wildlife agencies before reaching any decision on the GE mosquito.

A. Affected Species.

The species' habitat that may be affected by FDA's approval action includes, but is not limited to, Key Haven, Monroe County, Florida.

- The protected species of birds include, but are not limited to, the Everglade snail kite (*Rostrhamus sociabilis plumbeus*), Cape Sable seaside sparrow (*Ammodramus maritimus mirabilis*), Bachman's warbler (*Vermivora bachamanii*), Wood stork (*Mycteria americana*), Piping plover (*Charadrius melodus*), Roseate tern (*Sterna dougallii dougallii*), and Red knot (*Calidris canutus rufa*).

- The protected species of insects include, but are not limited to, Schaus swallowtail butterfly (*Heraclides aristodemus ponceanus*), Miami blue butterfly (*Cyclargus thomasi bethunebakeri*), Bartrams hairstreak butterfly (*Strymon acis bartrami*), and Florida leafwing butterfly (*Anaea troglodyte floridalis*).

- The protected species of mammals include, but are not limited to, Key deer (*Odocoileus virginianus clavium*), West Indian manatee (*Trichechus manatus*), Florida panther (*Puma concolor coryi*), Rice rat (*Oryzomys palustris natator*), Key Largo cotton mouse (*Peromyscus gossypinus allapaticoloa*), Key Largo woodrat (*Neotoma floridana smalli*), Lower Keys marsh rabbit (*Sylvilagus palustris hefneri*), and Puma (*Puma concolor*).

- The protected species of reptiles include, but are not limited to, American alligator (*Alligator mississippiensis*), Hawksbill sea turtle (*Eretmochelys imbricata*), Leatherback sea turtle (*Demochelys coriacea*), Loggerhead sea turtle (*Caretta caretta*), Eastern indigo snake (*Drymarchon coarais couperi*), American crocodile (*Crocodylus acutus*), and Gopher tortoise (*Gopherus plyphemus*).

- The protected species of fish include, but is not limited to, Atlantic sturgeon (*Acipenser oxyrinchus*).

- The protected species of snail include, but is not limited to, Stock Island tree snail (*Orthalicus reses*).

- The protected species of flowering plants include, but are not limited to, Blodgett's silverbrush (*Argytheamnia blodgetti*), Big Pine partridge pea (*Chamaecrista lineata keyensis*), Wedge spurge (*Chamesyce deltoidea serpyllum*), San flax (*Linum arenicola*), Garber's spurge (*Chamaesyce garberi*), Florida Pineland crabgrass (*Digitaria pauciflora*), Key tree cactus (*Pilosocereus robinii*), Cape Sable thoroughwort (*Chromolaena frustrata*), Florida prairie-clover (*Dalea carthagenensis floridana*), Florida semaphore cactus (*Consolea corallicola*), and Everglades bully (*Sideroxylon reclinatum ssp. sustrofloridense*).

As examples of these species, the Cape Sable seaside sparrow is a non-migratory bird that lives only in Florida and inhabits freshwater to brackish marshes.[2] Its restricted range is what led to its initial listing in 1967, and threats to its habitat posed by large-scale conversion of land to agricultural uses and changes in the distribution, timing, and quantity of water flows in South Florida continue to threaten the subspecies with extinction.[3] The bird is a dietary generalist meaning that it forages for a variety of insects and is opportunistic in nature.[4] Accordingly, the sparrow shifts the importance of prey items in its diet in direct response to their availability.[5]

The Bachman's warbler is the rarest songbird native to the U.S.[6] The bird has been in severe decline since its listing in 1967 due to loss of breeding and wintering habitat, as well as harvest for the millinery trade.[7] Information on its diet is unavailable; however it is believed to have an insect diet similar to other warblers.[8] Bachman's warbler was last seen in the U.S. in 1988, leading many to believe it is on the verge of extinction.[9]

For Piping plovers, food availability may be one of the reasons the species is in decline.[10] Piping plovers likely eat invertebrates and their diets vary depending on habitat type.[11] If Piping

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[2] FWS, Cape Sable Seaside Sparrow Multi-Species Recovery Plan for South Florida, at 4-345, https://www.fws.gov/verobeach/MSRPPDFs/CapeSableSeasideSparrow.pdf.
[3] *Id.* at 4-352.
[4] *Id.* at 4-351.
[5] *Id.*
[6] FWS, Bachman's Warbler Multi-Species Recovery Plan for South Florida, at 4-445, https://www.fws.gov/verobeach/msrppdfs/bachmanswarbler.pdf.
[7] *Id.*
[8] *Id.* at 4-447.
[9] *Id.* at 4-449.
[10] FWS, Piping Plover (*Charadrius melodus*) 5-Year Review: Summary and Evaluation, at 100 (September 2009),

plovers are unable to obtain a sufficient food source, it impacts their weight, which makes it more likely that they will not be able to avoid predators.[12] The other greatest threat to Piping plovers is human disturbance.[13] The wintering locations of the plovers in South Florida are plagued by pedestrian recreationists, their pets, and off-road vehicle enthusiasts.[14]

The Red Knot was recently listed by FWS in January 2015.[15] It is a migratory bird that travels as far north as the Canadian Arctic.[16] Red knots winter in Southern Florida where they forage for mollusks, insects, green vegetation, and seeds.[17] The knot's life history depends on suitable habitat, food, and weather conditions at far-flung sites across the Western Hemisphere.[18] If the birds do not encounter favorable habitat, food, and weather conditions within narrow seasonal windows during migration stops, it could further exacerbate their decline.[19]

Rice rats, or silver rice rats as they are commonly called, are unique to the Lower Keys.[20] Similar to the birds listed above, Rice rats are opportunistic when it comes to foraging for food. They are predominantly omnivorous, but preferably carnivorous, feeding mainly on insects, snails, and crabs.[21] Rice rats were listed as endangered in 1991 due to severe habitat loss from residential and commercial destruction, as well as the introduction or increase of non-native predators and competitors.[22]

In addition to the species listed above, GE mosquitoes may migrate beyond the test trial site of Key Haven, Monroe County, Florida, to neighboring counties by car, boat, or other conveyance, thereby potentially impacting other threatened and endangered species.

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https://www.fws.gov/northeast/endangered/PDF/Piping_Plover_five_year_review_and_summary.pdf.

[11] *Id.* at 101.

[12] *Id.*

[13] FWS, Piping Plover Multi-Species Recovery Plan for South Florida, at 4-331, https://www.fws.gov/verobeach/MSRPPDFs/PipingPlover.pdf.

[14] *Id.*

[15] FWS, Species Profile for Red Knot, ECOS Environmental Conservation Online System, https://ecos.fws.gov/ecp0/profile/speciesProfile?spcode=B0DM.

[16] Audobon, Guide to North American Birds: Red Knot (*Calidarus canutus*), http://www.audubon.org/field-guide/bird/red-knot.

[17] *Id.*

[18] *Id.*

[19] *Id.*

[20] FWS, Rice Rat Multi-Species Recovery Plan for South Florida, at 4-173, https://www.fws.gov/verobeach/MSRPPDFs/RiceRat.pdf.

[21] *Id.*

[22] *Id.* at 4-182.

B. FDA Has Taken Action that "May Affect" Listed Species and Their Designated Critical Habitat Without Consulting with the Expert Services.

Pursuant to the FDA approval, Oxitec would produce GE mosquito eggs in the United Kingdom (UK) and ship them to Marathon, Florida for rearing in the specialized Hatching and Rearing Unit (HRU). Once introduced into the HRU, the mosquitoes would be hatched and reared to pupae, which would be sorted mechanically to differentiate between males and females. Oxitec intends to only release male mosquitoes because they do not bite; however, the EA acknowledges that the sorting mechanism is not perfect, and in reality roughly 0.2% females will be released. EA at 16. The GE mosquitoes would then be released over a time period of up to twenty-two months. According to the EA, a minimum of 14,532,000 GE mosquitoes would be released over 104 weeks. EA at 29. Like its approval decision, FDA's conclusion concerning endangered and threatened species rests on an extremely limited inquiry that failed to adequately consider the significant risks of harm to listed species related to releasing millions of GE mosquitoes into the environment at the test trial site at Key Haven, Monroe County, Florida.

Because of this approval decision, for the first time ever in the U.S., millions of GE mosquitoes will be released into the environment, which may potentially harm threatened and endangered species. The ESA requires FDA to consult on these potential impacts. These threats are detailed in numerous comments to FDA, including comments from FWS. In its comments to FDA regarding the release of GE mosquitoes, FWS said:

> We [] recognize a possibility for conflicts with the conservation of native species (especially those that are listed as threatened or endangered under the Endangered Species Act (ESA)), and the potential negative consequences of releasing non-native (including some GE) organisms into the environment.

FWS recommended that FDA should require the applicant, as a condition of the permit, to: (1) when possible and appropriate, conduct field studies on the potential effects of the release to non-target organisms and the local native environment; (2) make the data available to regulatory agencies; and (3) whenever possible, publish the results in a peer reviewed journal in a timely many. FDA did not implement these recommendations as a condition of the permit.

The EA specifically acknowledges that birds, bats, amphibians, and predatory invertebrates eat mosquitoes. EA at 85-86. Thus, it is highly foreseeable that threatened and endangered species that maintain habitat in Monroe County may come into contact with and orally ingest GE mosquitoes. Moreover, many predators that consume mosquitoes are opportunistic, meaning that increasing the amount of mosquitoes in the area by the millions may change behavioral patterns of species that have access to an augmented food supply. If the trial is successful over the course of two years and the wild mosquito population is eventually suppressed by the introduction of non-native GE mosquitoes, it could result in a reduction of food supply for many predatory species, including threatened and endangered species.

FDA claims that threatened and endangered species will not be impacted by the release of millions of GE mosquitoes because "there was no overlap between threatened and endangered

species' habitat and the domestic or peri-domestic environment of *Ae. aegypti* in Key Haven."[23] EA at 46. This is incorrect factually and legally. The proper question is simply whether the species "may be present." FWS habitat maps for nearly all the species listed in Monroe County indicate that these species "may be present" in Key Haven. Not only did FDA apply the wrong standard, its assumption that protected species do not share the same habitat as *Aedes aegypti* mosquitoes is erroneous. The EA acknowledges that the *Aedes aegypti* habitat is not confined to a domestic or peri-domestic environment, but is rather diverse and includes water storage containers; flowerpots; waste materials such as tires, cans, and bottles; as well as boats, man-made containers at coastal edges; or on beaches. EA at 42. Considering the coastal nature of many of the species listed in Monroe County, it is clear that *Aedes aegypti* habitat overlaps with many listed species. These likely impacts far exceed the low threshold for actions that "may affect" listed species and trigger FDA's duty to consult with FWS and/or NOAA Fisheries regarding its approval of Oxitec's INAD application. FDA's failure to complete consultation with the expert fish and wildlife Services violates the ESA. For the same reasons, FDA also violated its independent duty to consult on the potential effects to any habitat designated as "critical" pursuant to ESA § 4(a)(3)(A). 16 U.S.C. § 1533(a)(3)(A).

C. FDA's "No Effect" Determinations are Arbitrary and Did Not Use the Best Scientific and Commercial Data Available.

Rather than consult with the Services after a "may affect" determination, FDA instead relied entirely on its own internal assessments of the risks to conclude that its approval of releasing GE mosquitoes into the environment will have "no effect" on any listed species or designated critical habitat.[24] FDA's "no effect" conclusion—and the process by which it reached that conclusion—violates the ESA.

FDA based its conclusions on its own inexpert—and fatally flawed—assumptions that GE mosquitoes released into the environment will not share the same habitat as threatened and endangered species, despite evidence that nearly all the protected species "may be present" at Key Haven, where the planned test trial is located. FDA even doubts its own assumption stating "even if any endangered species were to encounter [GE] mosquitoes … it is unlikely that [GE] mosquitoes would have a significant impact on predator species due in part to mosquitoes forming a small part of the predator's diet. Further … even if these species ingest a [GE] mosquito, the tTAV and DsRed 2 proteins in the [GE] mosquitoes lack any toxic potential and, therefore, do not pose any significant risks to non-target animals, including endangered species." EA at 46. FDA's reasoning shows that it contemplates that releasing millions of GE mosquitoes could affect threatened or endangered species, and yet FDA failed to consult the expert agencies. It is immaterial whether the impacts to threatened or endangered species are "significant;" the question is whether releasing GE mosquitoes "may affect" a listed species. FDA's conclusion

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[23] The only protected species that FDA believes "may be present" in physical vicinity of the proposed trial site is the Stock Island tree snail, and FDA unilaterally determined that the field trial is "not likely to adversely affect" the species as no removal or modification of habitat is proposed. EA at 46.

[24] FDA provided a copy of the EA to FWS for comments, but did not formally or informally consult the Services.

that the impact would not be significant should a protected species come into contact with a GE mosquito utilizes the wrong standard, and is therefore arbitrary and capricious. FDA also improperly relied on inaccurate information to determine the potential effects on listed species. 16 U.S.C. § 1536(a)(2) (requiring agencies to use only the best scientific and commercial data available).

FDA's "no effect" determinations are arbitrary and contrary to law because FDA did not consider impacts to threatened or endangered species and their habitats other than the Stock Island tree snail. FDA's erroneous conclusion that *Aedes aegypti* habitat does not overlap with the habitat of forty-two protected species in Monroe County is not supported by the evidence, and FDA is required to consult FWS and/or NOAA Fisheries prior to approving the release of millions of GE mosquitoes.

D. FDA's Determination that the Approval Is "Not Likely to Adversely Affect" the Stock Island Tree Snail Is Contrary to Law.

FDA may not unilaterally determine that its action is "not likely to adversely affect" (NLAA) a species without first engaging in Section 7 consultation, undertaking at least informal consultation, and culminating in a written concurrence from one of the expert wildlife agencies on that NLAA decision. 50 C.F.R. §§ 402.13(a), 402.14(b). That is, once FDA determines that a listed species "may be present" in the action area, it must stop and consult with the expert agency and enter into some form of consultation. Formal consultation is only not required if through informal consultation the expert wildlife agency agrees, in writing, that FDA's action will "not likely adversely affect" a listed species. *Id.* Accordingly, failure to consult and receive written concurrence is a violation of the procedures and substance of the ESA.

When FDA determined that the Stock Island tree snail would be in the physical vicinity of the proposed trial site, it was required to consult with FWS and receive a written concurrence from FWS that its action would "not likely adversely affect" the species. Instead, once FDA determined that the Stock Island tree snail was present in the action area, it relied exclusively on its own assessment that the action would "not likely to adversely affect" the species based on its assumption that the project would not remove or modify the snail's habitat. EA at 46. FDA's unilateral determination that its action is "not likely to adversely affect" the Stock Island tree snail and its failure to consult FWS is arbitrary and contrary to law.

VI. CONCLUSION

In sum, FDA's "no effect" findings, failure to consult, and unilateral determination that the action is "not likely to adversely affect" the Stock Island tree snail are arbitrary and capricious and violates the ESA because they fail to follow the ESA's mandated procedures, fail to use the best scientific and commercial data available, fail to consider significant aspects of the issue, and offer an explanation that runs counter to the evidence before the agency. For the above stated reasons, FDA has violated, and remains in ongoing violation of, Section 7 of the ESA. FDA is hereby notified that it has violated Section 7 of the ESA, 16 U.S.C. § 1536(a)(2), in at least the following ways:

Prior to approving the GE mosquito release, FDA failed to request from the expert agencies whether any threatened or endangered species, or designated critical habitat, may be present within or near the areas of the proposed actions. 16 U.S.C. § 1536(c)(1); 50 C.F.R. § 402.12.

Prior to approving the GE mosquito release, FDA failed to prepare a "biological assessment" to determine whether any threatened and endangered species that may be present within or near the areas of the proposed actions may be affected. 16 U.S.C. § 1536(c)(1); 50 C.F.R. § 402.12.

Prior to approving the GE mosquito release, FDA failed to consult with the expert fish and wildlife Services regarding the potential adverse effects of the GE mosquito on dozens of threatened and endangered species, and/or their critical habitat. 16 U.S.C. § 1536(a); 50 C.F.R. §§ 402.13-14.

Prior to approving the GE mosquito release, despite finding its action may affect at least one species, the Stock Island tree snail, FDA still failed to enter into consultation with FWS, and instead made an unlawful and unilateral "not likely to adversely affect" decision for that species, without the guidance and concurrence of the expert agency. 50 C.F.R §§ 402.13-14.

FDA has failed to insure, in consultation with the expert agencies, that its action is not likely to jeopardize the continued existence of any threatened or endangered species or result in the destruction or adverse modification of the critical habitat of such species. 16 U.S.C. § 1536(a)(2).

FDA has failed to insure that the agency or Oxitec will not make any irreversible or irretrievable commitment of resources with respect to the GE mosquitos prior to initiating and completing consultation with NOAA Fisheries. 16 U.S.C. § 1536(d).

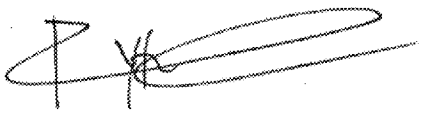
FDA has failed, in consultation with the expert agencies, to utilize its authorities in furtherance of the purposes of the ESA by carrying out programs for the conservation of endangered and threatened species, in violation of the ESA. 16 U.S.C. § 1536(a)(1). More specifically, FDA has failed to utilize its authorities to carry out programs for the conservation of the threatened and endangered species located in areas where GE mosquitoes will be released, in violation of the ESA. 16 U.S.C. § 1536(a)(1).

FDA's determination that its approval of Oxitec's INAD will have "no effect" on listed species is arbitrary and fails to use the best available science.

For the above stated reasons, FDA has violated and remains in ongoing violation of Section 7 of the ESA. If these violations of law are not cured within sixty days, the listed organizations intend to file suit against the responsible agency/agencies and officials to enforce the ESA, seeking declaratory and injunctive relief, as well as attorney and expert witness fees and costs. 16 U.S.C. § 1540(g)(4). This notice letter was prepared based on good faith information and belief after reasonably diligent investigation. If you believe that any of the foregoing is factually erroneous or inaccurate, please notify us promptly. Further, during the

notice period we are available to discuss effective remedies and actions that will assure future compliance with the ESA.

Sincerely,



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cc: Loretta Lynch, U.S. Attorney General